



By Mail (in duplicate)

August 28, 2002

File Ref: B18/2

Dockets Management Branch (HFA-350)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Dear Sirs,

**New FDA Regulations on Food and Drug Supply**  
**(Dockets Nos. 02N-0276, 02N-0277, 02N-0278)**

I refer to the letter of July 17, 2002 from Mr. Joseph Levitt, Director of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (FDA), concerning the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act).

You may wish to note that in Hong Kong, the Veterinary Public Health Section (VPHS) of the Food and Environmental Hygiene Department (FEHD) is responsible for inspecting and certifying locally manufactured food products being exported to the US, Canada, EU countries and Australia. We have a few comments regarding the provisions in Title III of the Act that we would like to bring to your attention:

**(i) Registration of Food Facilities**

We consider that food facilities could be inspected by the competent local government regulatory authority of the exporting countries under a set of FDA rules and guidelines. The FDA could send inspectors or preferably appoint trained local US embassy/consulate office staff to work with the competent local government regulatory authority from time to time as it deems necessary. Based on the report it receives from the competent local government regulatory authority, the FDA could then register those facilities that pass the inspection. The FDA may also consider getting inputs from the competent local government regulatory authority when setting up the relevant rules and guidelines.

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**(ii) Keeping of Records**

We consider that all food facilities should maintain a set of records as specified by the FDA. These records should be made available to the competent local government regulatory authority and/or authorized local US representative with short notice.

**(iii) Prior Notice of Food Shipments into the US**

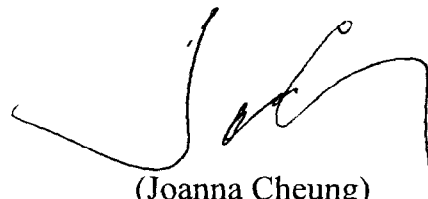
We consider that food products could only be shipped to the US with the appropriate import permits. Import permits would best be issued by the local US embassy/consulate office as they would have a better understanding of the local situation and could contact the competent local government regulatory authority, if necessary, to clarify any concern or question when issuing permits.

**(iv) Health Certificate for Certain Category of Food Items**

Like Australia and the EU countries, FDA can set up specific requirements for the manufacture of each product and the attainment of these requirements is to be certified by the competent local government regulatory authority of the exporting countries. For example, for Australia and EU countries, manufacturing of Chinese moon-cakes which contain animal parts (egg yolks) as ingredient has to be monitored and a health certificate has to be issued by the competent government authority in Hong Kong (in this case, a government veterinarian from VPHS of FEHD).

Please let me know if you require any further information.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Joanna Cheung', with a stylized flourish at the end.

(Joanna Cheung)  
Trade Specialist

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